Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit

Jon M. Sands
Federal Public Defender

Mridula S. Raman
Jessica M. Salyers
direct line: [redacted]
email: [redacted]

November 28, 2018

Governor Greg Abbott
State Insurance Building
1100 San Jacinto
Austin, Texas 78711-2428

Dear Governor Abbott:

As counsel for Joseph C. Garcia, I am writing to request an emergency 30-day reprieve from his execution, which is currently scheduled for some time after the hour of 6:00 p.m. (CST), on Tuesday, December 4, 2018. This request is made under Texas Administrative Code title 37 section143.41(a) and Article IV, § 11(b) of the Texas Constitution.

At approximately 4:30 p.m. (CST) on this day, counsel learned, via a news article (Ex. A), of allegations that the Texas Department of Criminal Justice (TDCJ) has potentially for the last three and half years obtained the drugs it uses to carry out lethal injections from a compounding pharmacy[1] that regulators have repeatedly cited for dangerous practices. The fact that Texas may be relying on a compounding pharmacy for pentobarbital, which is a sterile injectable, subjects our client, Joseph Garcia, to the unreasonable risk of a cruel execution. His concerns are not mere speculation; the pharmacy from which Texas may have obtained its supplies of

[1] Drug compounding is "the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved." Compounded drugs include "sterile injectables"—drugs that are intended to be injected into a person, and therefore must be sterile. *See Compounding and the FDA: Questions and Answers*, available at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm.

sterile-injectable pentobarbital has been repeatedly cited by the FDA and the Texas State Board of Pharmacy for safety violations in its compounding practices. (*See, e.g.*, Ex. B (FDA Warning Letter of Oct. 26, 2018 noting, e.g., "The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health . . . .); Ex. C (Texas State Board of Pharmacy, Warning Notice, March 27, 2017).) The pharmacy that may have supplied the drugs has been on probation in the past, even as recently as last year. (Ex. D.)

Reliance on such pharmacies is risky; indeed, as the FDA explains, compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."[2] Unsafe practices by compounding pharmacies have caused numerous public health crises over the years.[3] In 2012, injectable steroids produced by the New England Compounding Center (NECC) led to a tragic fungal meningitis outbreak across twenty states, infecting more than 800 individuals and resulting in 64 deaths.[4] An FDA inspection report of NECC facilities following the outbreak noted several alarming observations, including yellow and greenish residue lining on surfaces of equipment used in producing sterile drug products, "dark, hair-like discoloration" along the edges of a "Clean Room" used to formulate and fill sterile preparations, and multiple vials of sterile injectable drugs containing "greenish black foreign matter" and "white filamentous material."[5]

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[2] Compounding and the FDA: Questions and Answers, https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/PharmacyCompounding/ucm339764.htm.

[3] A Continuing Investigation into the Fungal Meningitis Outbreak and Whether it Could Have Been Prevented Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 113th Cong. 2 (2013) (statement of Margaret A. Hamburg, M.D., Comm'r, FDA) [hereinafter Hamburg Statement] (reporting multiple incidences over the past twenty years where compounded drugs have caused deaths and serious injuries).

[4] Kurt Eichenwald, Killer Pharmacy: Inside a Medical Mass Murder Case, Newsweek (Apr. 16, 2015, 7:07 AM), http://www.newsweek.com/2015/04/24/inside-one-most-murderous-corporate-crimes-us-history-322665.html.

[5] FDA, Form FDA 483 issued to Barry J. Cadden of New England Compounding Pharmacy Inc.

A subsequent FDA investigation of 55 compounding pharmacies found that more than 75% of those inspected had "serious issues," such as "lack of appropriate air filtration systems, insufficient microbiological testing, and other practices that create risk of contamination."[6]

Given the gravity of the allegations that counsel has recently learned about Texas's questionable practices regarding the procurement of pentobarbital and the danger of a constitutional violation during Mr. Garcia's execution, it is imperative that counsel have the opportunity to investigate the allegations against TDCJ and challenge as appropriate Texas's lethal injection protocol. As soon as counsel learned of these potential issues, counsel requested detailed information about how TDCJ obtained the chemicals that it plans to use to carry out his execution. (*See* Ex. E; Ex. F.)

Mr. Garcia was convicted of capital murder in Dallas County on February 13, 2003, in connection with the shooting death of Office Aubrey Hawkins. At the time of the writing of this letter, Mr. Garcia has a subsequent application for state post-conviction relief pending before the Texas Court of Criminal Appeals. In this Application, Mr. Garcia has challenged the validity of his death sentence on several constitutional grounds, including that the State presented misleading testimony during Mr. Garcia's capital sentencing in violation of the Due Process Clause of the Fourteenth Amendment; that Mr. Garcia, a Hispanic male, was denied a fair and impartial trial because his trial judge Vickers Cunningham harbors racial animus toward nonwhite people; that executing someone who neither killed nor intended to kill violates the Eighth Amendment; and that his trial counsel provided ineffective assistance during his capital trial proceedings in violation of the Sixth Amendment. Mr. Garcia also has an Initial Application for Writ of Habeas Corpus pending before the same court challenging the constitutionality of his 1996 non-capital conviction in Bexar County. Finally, on November 8, Mr. Garcia submitted an Application for Commutation of Death Penalty Sentence to Lesser Penalty And/Or 60-Day Reprieve to the Texas Board of Pardons and Paroles.

1, 7–8 (Oct. 26, 2012), http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf

[6] Hamburg Statement at 5.

For the reasons detailed above, going forward with Mr. Garcia's scheduled execution without permitting counsel to investigate the aforementioned allegations creates a grave risk that he will be put to death in violation of his Eighth Amendment right to be free from cruel and unusual punishment. Accordingly, Mr. Garcia respectfully requests a 30-day reprieve pursuant to Texas Administrative Code title 37 section 143.41(a) and Article IV, § 11(b) of the Texas Constitution.

Respectfully submitted,

Sincerely,

Mridula S. Raman
Assistant Federal Public Defender
Capital Habeas Unit

Jessica M. Salyers
Assistant Federal Public Defender
Capital Habeas Unit

MSR/JMS

EXHIBIT A

BuzzFeed News
REPORTING TO YOU

TRENDING

Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs.

Greenpark Compounding Pharmacy gave kids the wrong medicine. It forged documents. Its employees didn't wash their hands adequately. So why did the state with the most executions hire it to make lethal injection drugs?

Chris McDaniel
BuzzFeed News
Reporter

Posted on November 28, 2018, at 5:09 p.m. ET

Greenpark Compounding Pharmacy & Gifts in Houston.
Google

The Texas Department of Criminal Justice, which has carried out more executions than any other state, has for the last three and a half years bought drugs for lethal injections from a pharmacy that regulators have repeatedly cited for dangerous practices.

The source of the state's execution drugs has until now been a closely guarded secret. Texas, like other death penalty states, has a law that

prevents the disclosure of that information, making it impossible for the public to learn about the manufacturer's safety record. But documents obtained by BuzzFeed News indicate that one source is Greenpark Compounding Pharmacy in Houston, which has been cited for scores of safety violations in recent years. Its license has been on probation since November 2016, when the Texas State Board of Pharmacy found that it had compounded the wrong drug for three children, sending one to the emergency room, and forged quality control documents.

Questions about the source and quality of Texas's execution drugs have been particularly acute in the past year, since in their final moments of life, five of the 11 inmates who Texas put to death in 2018 said the drug they were injected with, which is supposed to be painless, felt like it was burning as it coursed through their bodies.

"I can feel that it does burn. Burning!" Anthony Shore said, his voice rising, as he died in January. Four months later, Juan Castillo swore and said the drug burned and that he could taste it in his throat. In the next few months, inmates Troy Clark, Christopher Young, and Danny Bible all made similar statements as they were dying. A sixth inmate, William Rayford, writhed and shook on the gurney after the drug began to flow into him.

Two more inmates are scheduled to be executed in coming days: Joseph Garcia on Dec. 4 and Alvin Braziel on Dec. 11.

Texas has faced growing difficulties in securing supplies of lethal drugs in recent years, as manufacturers have become increasingly unwilling to be associated with capital punishment, and the Food and Drug Administration has blocked surreptitious attempts to get the drugs from overseas. The manufacturer of pentobarbital, the substance Texas

uses in executions, requires its distributors to sign agreements that they will not sell their drugs to death penalty states. So Texas sought out a compounding pharmacy, which can combine the basic ingredients of known drugs according to a prescription for a specific patient — for example, a child who needs a medicine in a liquid rather than pill form. (The state has also tried importing drugs from a supplier in India, but the FDA seized the shipment.)

Compounding pharmacies are not subject to the same stringent federal standards as large manufacturers, and the products they make have a significantly higher failure rate and shorter shelf life, one measured in days, than conventionally manufactured drugs.

Attorneys for death row inmates have long warned that compounded pentobarbital could expire or degrade over time, putting their clients at risk of a painful death that would amount to torture.

“Improper compounding and testing procedures may leave fine particles undetectable by the naked eye in the solution, or larger particles that would not be detected by an untrained eye,” Dr. David Waisel wrote in a 2016 affidavit. “These particles can cause great irritation to the vein, resulting in extraordinary pain.”

The Texas Department of Criminal Justice has repeatedly dismissed the attorneys’ concerns, calling them “speculation upon speculation.”

Left: The gurney in Huntsville, Texas, where death row inmates are strapped down for lethal injection. Right: An exhibit at the Texas Prison Museum shows the three-chemical mixture used from 1982 until 2012, when it was replaced by a single drug.

Pat Sullivan / AP, Michael Graczyk / AP

In inspections by state regulators, Greenpark has been cited for 48 violations over the past eight years, according to documents obtained by BuzzFeed News. The violations included keeping out-of-date drugs in stock, using improper procedures to prepare IV solutions, and inadequate cleaning of hands and gloves.

Federal documents show that in November 2014, the Texas Department of Criminal Justice obtained, from an unnamed source, enough of the raw ingredient in pentobarbital to be used in hundreds of doses. The documents indicate that over the years, the state has transferred fractions of the ingredient to two compounding pharmacies, which use it to produce pentobarbital. The department first transferred 50 grams of the raw ingredient to Greenpark in April 2015, then again in February 2016. The documents indicate the state has not sent any of the ingredient to any other compounding pharmacy since then.

In a declaration it submitted under a pseudonym in June, Greenpark said it had supplied lethal injection drugs to Texas, and that the relationship "was and is contingent on" the pharmacy's "identity remaining a secret." If its identity became public, Greenpark wrote, it "will no longer conduct business with the Texas Department of Criminal Justice."

The other pharmacy that the documents indicate received shipments of the ingredient (80 grams of it in August 2015) remains unidentified. It's unclear which pharmacy supplied the compounded drugs for each

execution, but over the last three years Texas appears not to have acquired the drugs from any other sources.

BuzzFeed News shared the documents with two pharmaceutical experts who are familiar with such records. The experts confirmed the methodology behind the reporting.

Speaking by phone to BuzzFeed News, Ken Hughes, Greenpark's head pharmacist, said that his pharmacy had performed drug testing for the criminal justice department, but added, "It's none of your business what I do." Asked about the compounding of execution drugs, Hughes repeatedly said, "I don't do it."

When asked if that meant that the pharmacy, which also operates as a gift shop, does not do it currently or if it has never done so, Hughes said that he had two other calls on hold and ended the conversation. He did not respond to repeated follow-up emails or phone calls.

The Texas Department of Criminal Justice declined to comment.

It's unclear how the state selected Greenpark. Of the state's nearly 200 pharmacies that perform this sort of high-risk compounding, Greenpark is one of only eight that currently have their licenses on probation or revoked.

That probation, which is scheduled to expire at the end of this month, was put in place after a pharmacy technician made a mistake in compounding a batch of lansoprazole, a drug that can be used to treat high levels of stomach acid. Instead, the pharmacy gave three children lorazepam, a benzodiazepine similar to Xanax.

The state board found that one of the children had to receive "emergency treatment in a hospital after experiencing adverse effects,"

and that the pharmacy technician forged quality-control documentation. Without admitting or denying guilt, Hughes agreed to implement new procedures to prevent dispensing errors.

The parents of the child who went to the hospital after taking Greenpark's drugs sued the pharmacy in September 2017. Without admitting liability, the pharmacy settled, agreeing to pay $55,000 toward the child's college saving fund.

The FDA also inspected Greenpark in October 2017, and cited the pharmacy for several potential sterility violations. Greenpark said that it adhered to state pharmaceutical guidelines. Hughes added that the inspection has "given us an opportunity to review our procedures and look for improvements."

The FDA told BuzzFeed News it could not release its full report on Greenpark because doing so "could reasonably be expected to interfere with enforcement proceedings."

Chris McDaniel is an investigative reporter for BuzzFeed News and is based in New York. His secure PGP fingerprint is C90B B2EF E872 EF22 4EDA DABB 50E6 F2BE 1164 FCAF

Contact Chris McDaniel at chris.mcdaniel@buzzfeed.com.

Got a confidential tip? Submit it here.

EXHIBIT B

Greenpark Compounding Pharmacy 10/26/18

U.S. FOOD & DRUG ADMINISTRATION

Office of Pharmaceutical Quality
Operations, Division II
4040 N. Central Expressway,
Suite 300
Dallas, Texas 75204

October 26, 2018

CMS CASE #566233

WARNING LETTER

VIA UPS EXPRESS

Kenneth L. Hughes
Co-Owner and President
Prescription Labs, Inc.
dba Greenpark Compounding Pharmacy
4061-F Bellaire Blvd.
Houston, Texas 77025

Mr. Hughes:

From October 16, 2017, to October 27, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Prescription Labs, Inc., dba Greenpark Compounding Pharmacy, located at 4061-F Bellaire Blvd., Houston, Texas 77025. The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on October 27, 2017. FDA acknowledges receipt of your facility's response, dated November 30, 2017. Based on this inspection, it appears that you produced drug products that violate the Federal, Food Drug and Cosmetic Act (FDCA).

A. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA [21 U.S.C. § 351(a)(2)(A)]. For example:

1. Personnel were engaged in aseptic processing inside the ISO5 area with partially exposed skin and wearing non-sterile garb.

2. Personnel were observed re-sanitizing gloved hands with non-sterile **(b)(4)** before resuming aseptic processing inside the ISO 5 area.

3. The wipes used for disinfecting the interior of the ISO 5 hood are not sterile.

4. The certification of the ISO 5 classified areas is inadequate because there is no evidence it included non-viable particle counts.

5. Your firm failed to perform smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile are produced in an environment that may not provide adequate protection against the risk of contamination.

6. **(b)(4)** testing of the **(b)(4)** was not routinely performed for products intended to be sterile.

7. The use of **(b)(4)**-minute contact time for the use of **(b)(4)** as a sporicidal agent in the ISO 5 areas is inadequate.

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

B. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding some of the insanitary condition observations in the Form FDA 483, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. According to your response, you will "conduct a more comprehensive observation of competency assessments: Aseptic Technique." However, you did not provide any details of what the "more comprehensive observation" will entail and who would be conducting these observations. Furthermore, you did not include any timeframe or completion date for these assessments or what actions you intend to take if deviations are identified.

2. According to your response, you will "review with sterile compounding personnel, that sterile **(b)(4)** is the approved sanitizing solution." However, it is unclear how or when you intend to obtain the sterile **(b)(4)** since you did not include a receipt or a Certificate of Analysis (CoA) for the sterile **(b)(4)**. In addition, you did not provide any supporting training documentation for staff pertaining to the use of sterile **(b)(4)** in the aseptic processing areas.

3. According to your response, you will review with compounding personnel "the importance of process documentation for all **(b)(4)** testing." However, you did not provide any supporting training documentation for staff to ensure that they will be documenting and performing the test according to procedure. In addition, you have not provided safeguards to confirm that this process is documented appropriately in the future.

4. According to your response, you will "begin using **(b)(4)** Wipes" with a contact time "determined by the manufacturer." However, you did not provide a receipt, CoA, or the contact time being used for the wipes. Furthermore, you did not provide the expected date the **(b)(4)** wipes would be received or used within the ISO 5 areas or any information regarding the wipes being non-shedding. You also did not provide any personnel training documentation for this changed procedure.

Regarding other observations related to insanitary conditions, some of your corrective actions appear deficient:

1. In your response, you indicated that you comply with the “Texas State Board of Pharmacy and USP <797> requirements, to use lint free wipes in the clean room”; however, the practice of using non-sterile wipes in the ISO 5 hood can increase the potential for contamination to be introduced into the ISO 5 aseptic processing areas.

2. In your response, you indicated that you comply with the “Texas State Board of Pharmacy requirements regarding airflow smoke pattern Test.” However, you failed to commit to conducting new certifications or smoke pattern tests under dynamic conditions to show that ISO 5 areas can maintain unidirectional air flow. In response to this letter, please also include the non-viable particle counts as part of the new certifications.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A of the FDCA.

In addition, our review of the information collected during the inspection revealed the following:

1. You did not appear to use biological indicators (BI) during **(b)(4)** sterilization of finished drug products. Consequently, it is unclear if the sterilization conditions are adequate for inactivating all potential microbial contamination.

2. The **(b)(4)** is classified as an ISO 8, even though it is attached to an ISO 7 **(b)(4)** with an ISO 5 **(b)(4)** used for hazardous drug production. When an ISO 7 **(b)(4)** is negative to the **(b)(4)**, the **(b)(4)** should be classified ISO 7 or better to prevent ingress of lesser quality air.

3. Your media fills were not performed under the most challenging or stressful processing conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

C. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the

causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (**CMS Case #566233**). Please address your reply to John W. Diehl, Director, Compliance Branch, at the FDA address provided on bottom of first page of this letter. Additionally, please submit a signed copy of your response on your firm's letterhead via e-mail to ORAPHARM2_Responses@fda.hhs.gov.

If you have questions regarding the contents of this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.asente@fda.hhs.gov.

Sincerely,
/S/
Monica R. Maxwell
Program Division Director
Office of Pharmaceutical Quality Operations, Division II

Cc:
Allison Vordenbaumen Benz, Executive Director Texas State Board of Pharmacy
William P. Hobby Building, Suite 3-500 333 Guadalupe Street
Austin, Texas 78701

Nancy Hughes, Co-Owner Prescription Labs, Inc.
dba Greenpark Compounding Pharmacy 4061-F Bellaire Blvd.
Houston, TX 77025

More in Warning Letters

Page Last Updated: 11/13/2018
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA

EXHIBIT C

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3943
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 14713
Name of Facility Greenpark Compounding Pharmacy
Address 4061 F. Bellaire Blvd City Houston Zip 77025
Pharmacist License # 22586
NAME OF PERSON RESPONSIBLE Kenneth Lee Hughes

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(d)(14)(A)(iii)(III)
Explanation of violation Conduct and document filter integrity tests on all filters used to sterilize high risk or batch preparations. (de 87)

2. Law/Rule 291.133(d)(6)(B)(ii)
Explanation of violation Re-sterilization procedures for high risk sterile compounding must be completed in no worse than an ISO 8 environment. Hood last certified in June 2015. (de 239)

3. Law/Rule 291.133(d)(7)(D)(B)
Explanation of violation If the pharmacy prepares a low volume of hazardous preparations & is not located in a negative pressure room - it must employ two tiers of containment (i.e. closed ~~vial~~ vial transfer system (de 249)

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before April 27, 2017, disciplinary action may be instituted against your license.

by Kathy A. Salinas
Agent, Texas State Board of Pharmacy
Date 3-27-17

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [signature]

11/00

EXHIBIT D

last 6-23-15

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 14713

GREENPARK COMPOUNDING PHARMACY

License Information

License Status Probation
License # 14713
Expiration Date 12/31/2017
Date License Issued 12/31/1991

Address

4061 F BELLAIRE BLVD
HOUSTON, TX 77025
County HARRIS
Phone (713) 432-9855

Pharmacy Details

Prior Disciplinary Orders* Yes
ABO Summary is not available.

Either the Order summary has not been generated, or the Order contains confidential information which is not available to the public. Order summaries are updated on a quarterly basis.

View Order Details Below:

CQIP

- 271550 P14713 Greenpark Compounding Pharmacy ABO H16006 2016-11.pdf

Class of Pharmacy Community Sterile Compounding
Type of Ownership Corporation
Type of Pharmacy Community Independent
# of Hospital beds 0

* Information relating to disciplinary orders is current as of (30 days prior to this date).

A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to disclosure.

Employment Information

Pharmacist in Charge
HUGHES, KENNETH LEE

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No
Participates in the Texas Kids Insurance Program (SKIP)?	No
Translating services (Listed Below If Available)	

Spanish

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

No	**Nuclear**
Yes	**Out-Patient Prescriptions**
No	**Ship Prescription Out of State**
No	**Class D (Expanded Formulary)**
No	**Class D (Alternative Visit Schedule)**
Yes	**Compounding Sterile-Risk Level Low**
Yes	**Compounding Sterile-Risk Level Med**
Yes	**Compounding Sterile-Risk Level High**
Yes	**Compounding Non-Sterile**
No	**24 Hour Service** on call
No	**Closed Door**
Yes	**Compounding, Office Use**
Yes	**Home Delivery**
No	**Infusion**
No	**Pharmacist Administered Immunizations**
Yes	**Veterinary Prescriptions**

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status

BEHRMAN, KATHLEEN RIGSBY	22218	09/30/1976	02/28/2019	~~Staff~~ Relief	Active
HUGHES, KENNETH LEE	22586	06/02/1977	02/28/2019	PIC	Active
OLMSTEAD, ANGELA BAILEY	44342	07/20/2006	11/30/2018	Staff	Active
PAREKH, SEJAL DHAVAL	39095	04/22/2000	12/31/2017	Staff	Active
~~PHAM, JENNIFER TRANG~~	53234	07/11/2013	09/30/2017	Staff	Active
TIERNEY, ANGELICA AVILA	53418	07/18/2013	07/31/2017	Staff	Active

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Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
BUTLER, BRANDON	217504	03/18/2013	03/31/2019	Staff	Active
CLUBB, REBECCA ALICE	115233	05/14/2004	09/30/2017	Staff	Active
DEESE, DE'VON M.	130206	09/30/2005	10/31/2017	Staff	Active
DOOLEY, CAITLIN	256709	06/14/2016	06/30/2018	Staff	Active
PATIL, RANJEET RAMCHANDRA	199770	08/31/2011	08/31/2017	Staff	Active
TERRILL, LEANA LUCILLE	199074	08/08/2011	04/30/2018	Staff	Active
THURMAN, DAVID ROY	188322	05/12/2011	10/31/2017	Staff	Active

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Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 | 20 | No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
PRESCRIPTION LABS, INC.	OWNER	2623 LAKESIDE VILLAGE D	MISSOURI CITY	TX	77459
KENNETH LEE HUGHES	OFFICER	.			
NANCY N. HUGHES	OFFICER	.			

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The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

EXHIBIT E

Kim Stout

From: Dale Baich
Sent: Wednesday, November 28, 2018 7:13 PM
To: Sharon.Howell@tdcj.texas.gov
Cc: jason.clark@tdcj.texas.gov
Subject: Joseph Garcia, No. 999441 (execution date Dec 4, 2018)
Attachments: 2018.11.28 Baich-LDavis - flattened.pdf

Dear Ms. Howell,
Attached is a letter directed to Director Davis regarding Joseph Garcia, No. 999441. Mr. Garcia is scheduled to be executed on Tuesday, December 4. Please bring this matter to the Director's attention as expeditiously as possible.
Thank you for your assistance and courtesy.
Best regards,

Dale A. Baich
Office of the Federal Public Defender for the
District of Arizona, Capital Habeas Unit
602-382-2816 office
602-625-2111 mobile

EXHIBIT F

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit

Jon M. Sands
Federal Public Defender

direct line: 602-382-2816
email: dale_baich@fd.org

November 28, 2018

Lorie Davis
Director, Correctional Institutions Division
Texas Department of Criminal Justice
Huntsville, Texas 77342

Via email transmission to:
TDCJ General Counsel Sharon Howell: Sharon.Howell@tdcj.texas.gov

Dear Director Davis:

I represent Joseph Garcia, No. 999441, and in my capacity as his counsel, I write to ask that the Texas Department of Corrections and Justice provide me with notice of the source from which TDCJ has acquired or intends to acquire the pentobarbital[1] or any related chemical[2] (hereinafter "lethal drugs") that it intends to use in Mr. Garcia's execution, which is scheduled for Tuesday, December 4, 2018. I am making this request because a news story was published today that indicates that TDCJ obtains its pentobarbital from a compounding pharmacy that has been cited by the FDA for multiple safety violations in its compounded products.[3]

Specifically, I request the following information for the pentobarbital that TDCJ has in its possession or will order for use in Mr. Garcia's execution, whether or not those drugs were originally ordered for use in his execution.

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[1] If TDCJ intends to use a drug other than, or in addition to, pentobarbital, please make the same disclosures for that drug(s) that I request for pentobarbital.

[2] *E.g.*, any API (Active Pharmaceutical Ingredient) or other substance necessary to make pentobarbital or any other substances TDCJ will use or intends to use in the execution of Joseph Garcia.

[3] Chris McDaniel, "Inmates Said The Drug Burned As They Died. This Is How Texas Gets Its Execution Drugs." Buzzfeed, Nov. 28. 2018, https://www.buzzfeednews.com/article/chrismcdaniel/inmates-said-the-drug-burned-as-they-died-this-is-how-texas?utm_term=.pkxy4410jP#.pkxy4410jP

1. If TDCJ ordered or will order the drug or chemicals from a supplier, please provide a copy of the order forms used. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date that the order was placed, the quantity ordered, the name of the supplier, the address to which the order was shipped, and the date that TDCJ received the order.

2. If TDCJ obtained or will obtain the drugs or chemicals via a prescription, please provide a copy of each prescription for each drug or chemical. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the superscription (including the date that the prescription was issued), the inscription, the subscription, the signatura, and any refill information. If the prescriptions were filled from presigned order sheets, please provide a copy of those documents as well.

3. If TDCJ obtained or will obtain the drugs or chemicals by some means other than ordering through a supplier or through a prescription, please provide all documentation pertaining to that manner of acquisition. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date the drugs or chemicals were ordered and acquired, the source that provided the drugs or chemicals, and the legal authorization by which the source was permitted to transfer the drugs or chemicals to you. This request encompasses, but is not limited to, letters requesting or authorizing transfer of the drugs or chemicals; and all logs pertaining to the issue, including drug logs, property logs, and chain-of-custody logs.

4. A copy of the prescription label from each drug or chemical obtained or already possessed by TDCJ. The physician's name and DEA registration number may be redacted. All other information must be legible, including-but not limited to-the date the prescription was originally filled, the original number of refills, the date the prescription was last refilled, the number of refills remaining, and the prescription number.

5. A copy of all drug logs pertaining to each drug or chemical. Physicians' names and DEA numbers may be redacted. Additionally, the names of persons for whom the drugs or chemicals were used may also be redacted. However, all other information must be legible, including-but not limited to-the dates on which any of the drugs or chemicals were used; the amount remaining of the

drug or chemical after each use; and the purpose for which the drug or chemical was used.

6. A copy of the package label, including the lot number and expiration date, for each drug or chemical obtained or already possessed by TDCJ. If the lot number or expiration date does not appear on the package label, please also provide a copy of that information from the appropriate location on the package. All information must be legible.

7. All chain-of-custody information for each drug or chemical obtained or already possessed by TDCJ, from the time the drug or chemical was dispensed, to the current time. This information should include all details pertaining to person-to-person transfer of the drugs (the names of involved individuals may be redacted); the date and time any transfers were made; the time in possession by each individual who handled the drug or chemical; the manner in which the individual(s) transported the drug or chemical (e.g., via automobile, airplane, etc.); and the amount of time each drug or chemical spent in transport.

8. All information about the storage of each drug or chemical obtained or already possessed by TDCJ, *from the time of dispensing to the current time*. This information must include the storage location; the storage temperature; and the means by which the storage temperature was ensured, maintained, determined, and recorded. All information must be legible.

9. If any of the drugs or chemicals have already been mixed or otherwise prepared, provide the date and means of preparation, and provide the same storage information for the prepared dose(s) as listed above, #8.

10. All information relating to testing by any facility of the API and finished drug products.

This request is ongoing. As you receive information relevant to this request, please provide it to me immediately via email at dale_baich@fd.org.

Given the documentation in the media relating to the problems with the pharmacy identified as the business that supplies TDCJ with execution drugs, I am requesting this information so I can advise Mr. Garcia of the status of relevant facts pertaining to the manner and means by which his execution will take place.

Mr. Garcia has a due-process right to be informed about the manner and means by which his execution will take place. *See Oken v. Sizer*, 321 F. Supp. 2d 658, 665 & n.5 (D. Md. 2004) (requiring production of execution protocol and stating. "[d]ue process requires . . . an opportunity to receive notice of how one's rights will be affected and opportunity to respond and be heard."), *stay vacated*, 542 U.S. 916 (2004).

Mr. Garcia has the right to know whether and how TDCJ has obtained the proper chemicals so that he may determine how his rights will be affected, and may seek the appropriate opportunity to respond and be heard. Due to the immediacy of Mr. Garcia's execution, I ask that you respond as quickly as possible.

Sincerely,

Dale A. Baich
Attorney Supervisor
Capital Habeas Unit

DAB/kls

cc: Jason Clark, Chief of Staff, Jason.Clark@tdcj.texas.gov